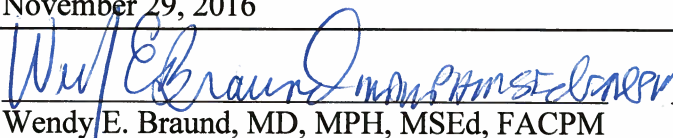




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Governor Matthew H. Mead

Policy Title:	Vaccine Restitution Policy
Effective Date:	January 1, 2017
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Approval:	 Wendy E. Braund, MD, MPH, MEd, FACPM Date <u>1/9/17</u>

Introduction

The Public Vaccine Programs (PVP) are important to the health and well-being of Wyoming children and adults. The Vaccine Restitution Policy is essential to ensure that publicly-supplied vaccine is not wasted, expired, spoiled, or lost and every dose is used to protect Wyoming residents against vaccine-preventable diseases. Vaccine loss is both costly and preventable.

Providers enrolled in a PVP are responsible for maintaining appropriate temperatures and vaccine quality from the time a shipment arrives until the vaccine is administered. The Immunization Unit provides no cost education regarding vaccine storage and handling practices at any time to immunization providers to ensure that staff understand the importance of effective vaccine storage and handling processes. PVP providers are required to report all wasted, expired, spoiled, or lost vaccine to the Immunization Unit immediately. Providers must also report when public vaccine is exposed to temperatures outside of the allowable range to the Immunization Unit immediately upon discovery.

This document serves as the Immunization Unit's policy for management of incidents that result in the loss of federal or state supplied vaccine. In instances where it was determined that vaccine loss was caused due to a provider's negligence or failure to respond, providers will be required to complete a dose-by-dose replacement of the wasted publicly-supplied vaccine. Alternative and/or additional actions may be taken at the discretion of the Immunization Unit, with input from the State Health Officer and/or Director of the Wyoming Department of Health or his/her designee. Monetary restitution for vaccines purchased with federal funds cannot be accepted.

Definitions of Vaccine Loss Terms

Expired or spoiled vaccine: Nonviable vaccine in its original container (vial or syringe) that is able to be returned for excise tax credit. This includes expired vaccine or vaccine that has been spoiled as a result of the following:

- Natural disaster/power outage
- Refrigerator too warm or too cold
- Failure to store properly upon receipt
- Vaccine spoiled in transit
- Mechanical failure
- Spoiled-other
- Recall

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Expiration date: The last date on which the vaccine may be used; expired vaccine includes vaccine that is past the manufacturer's expiration date on the vial or expiration date after reconstitution, depending on the vaccine and according to manufacturer instructions.

Wasted vaccine: Nonviable vaccine that is NOT able to be returned to the vaccine distribution center. This includes:

- Vaccine drawn into a syringe but not administered
- Vaccine in open vial but doses not administered
- Compromised vial (e.g., due to a drop causing damage to the vial integrity or sterility), broken vial

Lost vaccine: Any vaccine that was delivered to a provider's office but cannot be located.

Note: The Immunization Unit has the capability of tracking all vaccine shipments from the vaccine distribution facility to a provider's office.

Vaccine Restitution Policies and Procedures

Vaccine restitution will be required in situations where it is determined by the Immunization Unit, with the approval of the State Health Officer that the vaccine loss was due to provider negligence. This negligence may be due to improper inventory management, including failure to rotate stock resulting in expired vaccine, improper storage and handling, or failure to respond to out of range temperatures immediately upon discovery.

In instances where publicly-supplied vaccines may have been compromised, providers must "quarantine" the vaccines in question by marking them "Do Not Use" and continue to store them at proper temperatures until viability can be determined by the vaccine manufacturers in conjunction with the Immunization Unit. **Note: Providers are responsible for conducting stability or viability investigations for privately-purchased vaccines.**

Once a provider has received formal notification of vaccine restitution, the replacement may take place through either of the following methods:

- A vaccine transfer from private stock to public stock.
- Requires vaccine reconciliation and entry into the Wyoming Immunization Registry (WyIR) with vaccine indicated for public use.
- This method requires approval of data logger thermometer temperature data for the unit that currently stores the private vaccine to be used as public.
- The purchase of vaccine with private funds to be administered to patients who are eligible for the specific Public Vaccine Program.
- Requires submission of vaccine purchase order and packing slip, as well as a report of vaccine lot numbers to the Immunization Unit.
- Entry of the replacement vaccine in the WyIR.

Both methods require that the vaccine be physically labeled as public stock and stored with other publicly-supplied vaccines. The Immunization Unit must be notified when vaccine replacement has taken place so that the replacement can be confirmed.

Providers must re-vaccinate following the administration of nonviable vaccine as a result of failure to keep the vaccine viable. If the nonviable vaccine was due to provider negligence, this re-vaccination must occur with private stock vaccine, purchased by the provider.

Failure to report vaccine loss to the Immunization Unit upon discovery may result in suspension from one or more of the Public Vaccine Programs. If it has been determined that vaccine loss could have been prevented, the Immunization Unit will formally notify the provider and include the steps that must be taken in order to replace the publicly-supplied vaccines. Vaccine replacement shall occur within a period of no more than 90 days from the date the provider is notified by the Immunization Unit.

Expired vaccine amounting to greater than ten (10) doses of any one vaccine in a 30 day period will require replacement of all expired doses including the original ten (10).

Situations That May Require Vaccine Replacement

Vaccine replacement may be required in, but is not limited to, the following situations:

- Pre-drawn vaccine that is not used.
- Failure to prevent expired vaccine by:
 - a. rotating vaccine stock within the storage unit by expiration date to ensure staff use vaccine that will expire first prior to vaccine that will expire later, or
 - b. transferring vaccine to another provider to use prior to expiration.
- Failure to store vaccine at proper temperatures.
- Refrigerator or freezer was left unplugged.
- Refrigerator or freezer door was left open or ajar.
- Power outages in which the provider fails to take precautions (e.g., not following an established emergency plan).
- Failure to respond to a storage unit alarm immediately upon notification.
- Failure to report out of range temperatures to the Immunization Unit immediately upon discovery.

Lost Vaccine

- Vaccine that is signed for by a staff member at the provider office upon delivery but cannot be located.

Appeals Process

If a Public Vaccine Program provider disagrees with the determination of provider negligence, the provider may submit a written appeal to the State Health Officer within ten (10) business days of formal notification of vaccine replacement.

Replacement appeals must be signed by the Responsible Physician listed on the PVP Provider Agreement. Upon receipt of the appeal, the Immunization Unit will convene a review committee to review the appeal, the circumstances of the vaccine loss, and any other relevant information. Providers who appeal the determination will receive written notification regarding the outcome of the appeal within thirty (30) calendar days of receipt of the appeal request. Vaccine replacement activities will be

on hold and the provider may remain in a Public Vaccine Program during the appeal review period as long as there is no further risk to vaccine viability.

Procedures for Returning Nonviable Vaccine

PVP providers must return all unopened vials and manufacturer's pre-filled syringes of non-viable vaccine to the vaccine distribution center regardless of any financial restitution status applied to the vaccine. Vaccine provided through a Public Vaccine Program should never be discarded unless they do not qualify for return).

Public Vaccine Program providers should follow the procedures outlined by the Immunization Unit to report vaccines that qualify for return to the vaccine distribution center. All vaccine loss must be appropriately reconciled out of the WyIR.

If you have any questions concerning this policy, please call the Immunization Unit at 307-777-7952.